

### CERTIFICATE OF ANALYSIS

|  |                                 |  |
|--|---------------------------------|--|
| <b>Product Name:</b> Streptococcal Grouping Reagent Latex Suspension Group B | <b>Lot Number:</b> C10557B      |  |
| <b>Product Code:</b> PL.032  | <b>Expiration Date:</b> 2014 11 |  |


#### Additional Information

|                     |                               |
|---------------------|-------------------------------|
| Storage Conditions: | 2-8°C                         |
| Precautions:        | Refer to Instructions for Use |

#### Quality Control Testing

| Appearance  | Reaction | Result       |
|---|----------|--------------|
| Homogenous suspension with no agglutination           | N/A      | Satisfactory |
| <b>Organisms</b>                                      |          |              |
| <i>Streptococcus agalactiae</i> ATCC 12386 (Group B)  | Positive | PASS         |
| <i>Streptococcus agalactiae</i> ATCC 13813 (Group B)  | Positive | PASS         |
| <i>Streptococcus</i> Group B - Clinical Isolates      | Positive | PASS         |
| <i>Streptococcus pyogenes</i> ATCC 19615 (Group A)    | Negative | PASS         |
| <i>Streptococcus equisimilis</i> ATCC 12388 (Group C) | Negative | PASS         |
| <i>Enterococcus faecalis</i> ATCC 49477 (Group D)     | Negative | PASS         |
| <i>Streptococcus</i> sp. ATCC 12392 (Group F, type 2) | Negative | PASS         |
| <i>Streptococcus</i> sp. ATCC 12394 (Group G)         | Negative | PASS         |
| <i>Escherichia coli</i> ATCC 25922                    | Negative | PASS         |
| <i>Staphylococcus aureus</i> ATCC 25923               | Negative | PASS         |
| <i>Haemophilus influenzae</i> ATCC 10211              | Negative | PASS         |
| <i>Streptococcus pneumoniae</i> ATCC 49619            | Negative | PASS         |
| <i>Listeria monocytogenes</i> NCTC 11994              | Negative | PASS         |
| <b>Control</b>  |          |              |
| Polyvalent Positive Control (PL.040)                  | Positive | PASS         |

#### Release

|            |  |
|------------|--|
| 2013 06 17 |  |
| Date       | Quality Control  |